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ORIGINAL RESEARCH

Evaluation of the onset of pulpal, soft tissue anesthesia, and pain using buffered lidocaine in children: a randomized-controlled trial

Rouaa Hassan[1,*], Chaza Kouchaje[1,†], Hanadi Almattit[2,†], Ibrahim Alnassar[1]

[1]Department of Pediatric Dentistry, College of Dentistry, Damascus University, +963 Damascus, Syria
[2]Department of Biochemistry, College of Medicine, Damascus University, +963 Damascus, Syria

***Correspondence**
rouaa.hassan@damascusuniversity.edu.sy (Rouaa Hassan)

† These authors contributed equally.

Abstract

The American Academy of Paediatric Dentistry (AAPD) has recently released guidelines that highlight the importance of conducting further research on the effects of buffered local anesthesia in children. Adjusting the pH of local anesthetics may reduce pain and reduce the onset time of anaesthesia. In this study, we evaluated the onset of pulpal, soft tissue anesthesia and pain during inferior alveolar nerve block injection to treat pulpally involved mandibular primary molars with buffered lidocaine in comparison with non-buffered lidocaine. We conducted a prospective, randomized, triple-blind, crossover trial involving 40 children aged 7 to 10 years. The onset time of soft tissue anaesthesia was assessed by probing the gingiva after ensuring numbness of the tongue, the lower lip, and the angle of the mouth, while the onset time for pulpal anaesthesia assessed using Endo-ice. We identified a significant difference between buffered lidocaine and non-buffered lidocaine in the onset time of pulpal and soft tissue anesthesia ($p < 0.001$). Analysis also identified a showed a significant difference between the two groups for the Wong-Baker Faces pain rating scale ($p < 0.006$) and the Sound, Eye and Motor scale ($p < 0.043$). In conclusion, buffered lidocaine reduced the onset time for anaesthesia in pulpal and soft tissue, and reduced pain during the administration of inferior alveolar nerve block injections in children. According to the findings of this study, buffered lidocaine can be utilized as an alternative to non-buffered lidocaine in children.

Keywords

Buffered lidocaine; Children; Inferior alveolar nerve block; Lidocaine; Local anesthesia

1. Introduction

Malamed defined local anaesthesia as the transient loss of sensation in a specific area of the body caused by the depression of nerve-ending excitation or the inhibition of conduction in the peripheral nerves [1]. Although various aesthetic techniques have been used to achieve effective anaesthesia in the mandibular molars during dental surgery, inferior alveolar nerve block (IANB) remains as the primary method to achieve anaesthesia in the mandibular region; this is due to its safety, reliability, and delivery efficacy of the target solution [2]. However, IANB has been reported to be the most painful and stressful aesthetic technique in dentistry [3].

Many drugs, including bupivacaine, lignocaine and etidocaine, have been used to provide local anaesthesia in dentistry. However, most dental practitioners continue to utilise lidocaine [4]. In the absence of clinical conditions, the pH of the human body ranges from 7.35 to 7.45, with an average pH of 7.40. A pH $<$7.35 is considered to be acidic, whereas a pH $>$7.45 is considered to be basic [5]. Vasoconstrictors enhance the depth of anesthesia and improve local anesthetic safety. However, they are rapidly oxidized at physiological pH values; thus, sodium bisulphate ($NaHSO_3$) is added to the solution as an antioxidant, thus raising the acidity of the solution to preserve stability, water solubility and prolonging shelf life [6, 7]. The pH of plain lidocaine is approximately 5.7–6.5 while the pH of lidocaine containing vasoconstrictors is approximately 3.5–5.5 [8].

The pain caused by the local administration of anaesthesia has been attributed to many factors, including the speed of injection, the site of injection and the pH of the anaesthetic solution [9]. Thus, the administration of local anaesthesia causes pain when pricking the mucosa with a needle and a burning sensation from the acidity of the anaesthetic that causes local irritation [7]. Local anaesthetic molecules are provided in either ionized and non-ionized forms. Due to the solubility of the non-ionized form in lipids, it can easily cross neuronal membranes and block sodium channels. When sodium channels are blocked, pain is not felt or communicated. The relative proportion of ionic forms depends on the dissociation constant (pKa) of the specific local anaesthetic [10]; the pKa of lidocaine is 7.7 [11].

Research has shown that more of the active drug (for the

unionized form) is available when the pH of the injected local anesthetic is closer to the pKa of the drug [10]. It has been proposed that neutralization of the pH of the local anesthetic solution by buffering with sodium bicarbonate prior to injection may immediately reduce pain, shorten the onset time, and improve the clinical efficacy of local anesthesia [12]. Many studies using buffered local anesthetics have been performed in ophthalmology, audiology, nose and throat medicine and dermatology [13]. Patients receiving buffered lidocaine have been proven to experience less pain following intradermal injections also showed a preference for buffered solution when compared to unbuffered lidocaine [9].

Different local anesthetic solutions to sodium bicarbonate concentrations have been employed to buffer local anesthetic solutions, with a 1:10 ratio being the most popular [4]. Moreover, when sodium bicarbonate is mixed with a local anesthetic solution, its interaction with hydrochloric acid in the local anesthetic leads to the generation of water and carbon dioxide. Carbon dioxide potentiates local anesthesia through three possible mechanisms: a direct depressant effect on the axon, the concentration of local anesthetic inside the nerve trunk, and by reducing the pH inside the nerve, thus leading to greater conversion of the anesthetic to cations inside the membrane [12].

This study aimed to evaluate the onset of pulpal and soft tissue anesthesia and pain perception during inferior alveolar nerve block injections in children. To our knowledge, this is the first study to evaluate the onset of pulpal and soft tissue anaesthesia in children using this particular technique. Previous clinical trials investigating the efficacy of buffered lidocaine in children evaluated the onset time of anaesthesia based on soft tissue anaesthesia; however, this is not an assurance for pulpal anaesthesia.

2. Materials and methods

The study was designed as a triple-blind, split-mouth, randomised controlled trial in which the statistician; the investigators who assessed the Sound, Eye and Motor scale; and the children and their guardians, were all blinded.

First, we used G*Power version 3.1.9 software from Heinrich Hein University in Düsseldorf, Germany (https://www.hhu.de) to determine the sample size required for statistical power. Pain on injection was considered to determine the effect size, as based on a previous study by Torres-Rojas *et al.* [14] (2023); the effect size was 0.73. The sample size calculation required a sample size of 31 children to detect a significant difference (with 80% power and at a 5% significance level). This number was increased to 40 children, requiring a total sample size of 80 IANB injections (female: n = 21; male: n = 19). The mean age was 7.88 ± 1.017 years (mean ± SD) with a range of 7 to 10 years (Fig. 1).

The following inclusion criteria were used to include a total of 40 patients who were suitable to undergo at least two clinical sessions of endodontic treatments requiring inferior alveolar nerve block anaesthesia: (1) healthy children; (2) children between the ages of 7 and 10 years; (3) cooperative children according to the Frankel behavior rating scale (positive or definitely positive); (4) primary mandibular molars (at least one primary molar on each side) requiring pulp therapy, (5) vital pulp according to the Endo-ice test.

We also applied the following exclusion criteria: (1) patients with a history of medically compromising conditions; (2) children who exhibited allergic reactions to any component of local anesthesia (lidocaine, epinephrine, Sodium bicarbonate); (3) the presence of any clinical or radiographic signs that indicate pulp necrosis; (4) children who had only one primary mandibular molar (unilateral) requiring pulp therapy; (5) children who did not return the following week to complete the second session of anaesthesia.

Folded cards with numbers ranging from 1 to 40 were used to randomise the anaesthetic solution (buffered or unbuffered) used during the first session. The first twenty digits represented patients who received non-buffered lidocaine in the first session and buffered lidocaine in the second session, which were scheduled one week apart (Fig. 1).

3. Procedures

In this study, we recruited children with bilateral mandibular primary molars impacted by severe dental caries requiring pulp therapy. Patients received a complete clinical examination. We also obtained apical radiographs of the affected teeth at the initial session.

Before administering anesthesia, the dentist checked the right or left mandibular primary molars for pulpal vitality by measuring their sensitivity to cold using chloroethyl Endo-Ice (Maquira, www.maquira.com.br, Brazil). The opposed primary molar was also checked for vitality using the same technique to familiarise the participant with the cold sensation.

Children were shown and familiarised with the Wong-Baker FACES Pain Rating Scale (WBS), thus allowing them to effectively establish a baseline score for their pain perception (Fig. 2). Each face on the WBS scale was explained to the child, ranging from 0 which represents a person who is pleased because he/she is pain-free, to 10 which represents unhappy because he/she is in a lot of pain [15].

The anesthetic solution for use in the first session was chosen at random, beginning with the patient's principal complaint. To reduce the discomfort caused by administering the local anesthetic, a topical anesthetic agent (Procaine-B, 20% Benzocaine) was applied to the injection site for one minute prior to the injection; this is active on soft tissue surfaces that are 2–3 mm deep [16]. As recommended by Malamed *et al.* [17] (2020), 1.8 mL of IANB solution was injected using a 27-gauge needle over a period of 60 seconds. To reduce variation, including injection speed, all injections were administered by a single doctor (one of the authors). We used 1.8 mL cartridges of 2% lidocaine and 1:80,000 epinephrine (traditional dentistry local anesthetic cartridges) (Huons Co., Ltd, https://huons.com, Korea) as the control solution. The test solution consisted of cartridges containing 2% lidocaine and 1:80,000 epinephrine, buffered at a 1:10 ratio with 8.4% sodium bicarbonate. A disposable 1 mL syringe was used to aspirate 0.18 mL from the conventional lidocaine cartridge (lidocaine 2% epinephrine 1/80,000) under sterile circumstances. Another 1 mL sterile and disposable syringe was then used to add 0.18 mL of 8.4% sodium bicarbonate

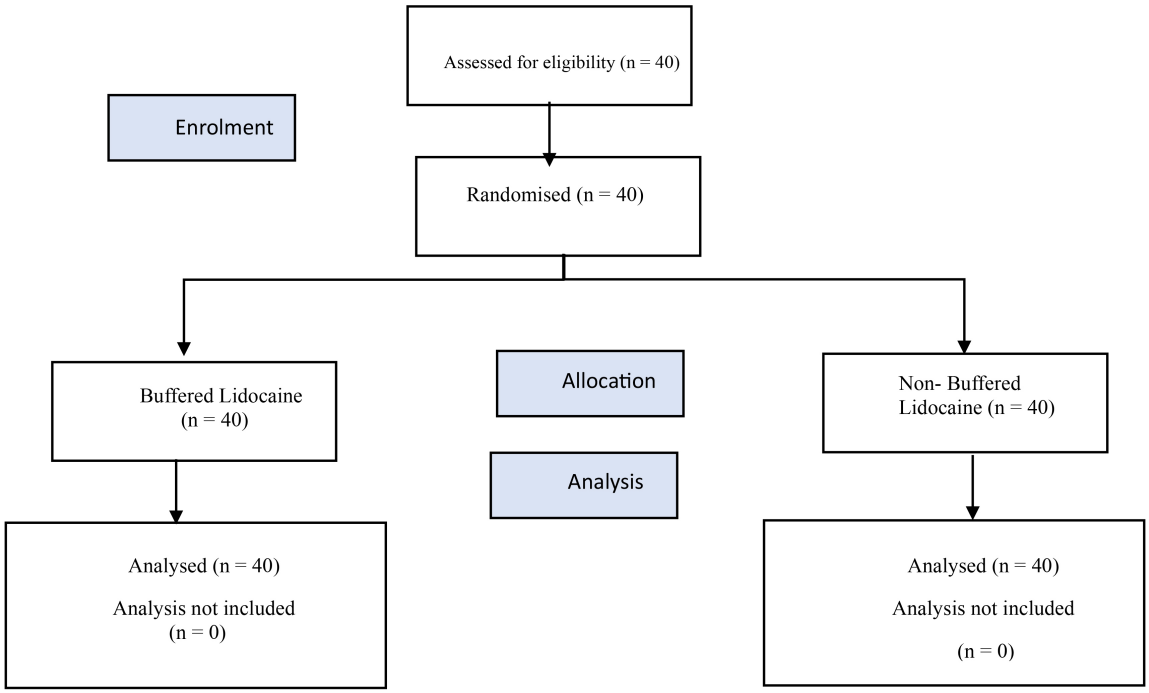

FIGURE 1. Consort flow diagram. n: number.

FIGURE 2. Wong-baker faces® pain rating scale.

to the same cartridge, diluting it by 1:10. To ensure that the sodium bicarbonate was fully dissolved fully, the container was shaken until the mixture was clear (Fig. 3).

The child was asked to point at the face that most closely represented the perceived pain after receiving the IANB injection; this strategy was used to subjectively quantify pain during the administration of anesthesia. The number associated with the chosen face was then recorded (Fig. 2). The administration of anesthesia was videotaped, and three external investigators, all of whom were pedodontists, evaluated each patient's reactions using the Sound, Eye and Motor (SEM) scale to assess the pain objectively (Table 1).

To assess the onset time of soft tissue anesthesia, each child was asked about the numbness in their tongue, lower lip, and the angle of the mouth. After ensuring numbness, the onset time for soft tissue anesthesia was assessed by probing the gingiva every 15 seconds. The dentist then applied Endo-Ice to a cotton pellet against the cervical third of the buccal surface of the examined tooth as soon as soft tissue anesthesia was established. The dentist then asked the child to identify sensations every 15 seconds until the child no longer felt the cold. The follow-up appointment was planned for at least a week later when the same data were evaluated and the other anesthetic solution was administered on the contralateral side. Finally, statistical analysis was performed on the data collected for each parameter.

4. Statistical analysis

SPSS software version 24 (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY, USA: IBM Corp, 2016) was used for all statistical analysis and graphs were created in Excel (Microsoft Office, Dubai, United Arab Emirates, 2016). Kolmogorov-Smirnov, was used to verify the normality of the

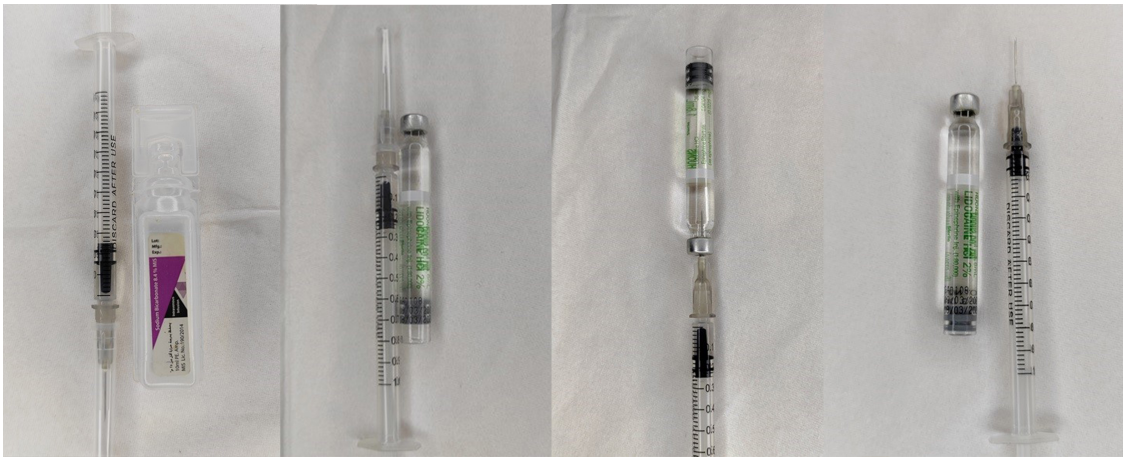

FIGURE 3. Preparation of buffered lidocaine.

TABLE 1. Sound, eye, motor (SEM) scale.

Parameter	Comfort	Mild discomfort	Moderate discomfort	Severe discomfort
Grade	1	2	3	4
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint, Shouting, crying
Eye	No sign	Dilated eye without tear (anxiety sign)	Tears, sudden eye movements	Crying tears all over the face
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defence, turning the head to the opposite side

research sample data. The onset time of soft tissue and pulpal anesthesia with buffered lidocaine and non-buffered lidocaine were compared using the independent sample student's *t*-test. Data acquired from the Wong-Baker facial pain scale and the Sound, Eye and Motor scale were used to identify differences in pain between the two groups using the Mann-Whitney test. $p < 0.05$ was considered statistically significant.

5. Results

5.1 Pain on administration

5.1.1 Wong-baker faces pain rating scale

Results arising from the WBS pain rating scale are shown in Table 2. When using buffered anesthetics, 72.5% of patients had pain scores of 0, whereas 0% had scores of 6. In comparison, 5% of the patients treated with non-buffered anesthetics had a pain value of 6; 12.5% had a pain value of 4 (Table 2).

The Mann-Whitney test revealed a significant difference in the WBS pain rating scale between buffered and non-buffered anesthetics (Table 3, $p = 0.006$).

5.1.2 Sound, eye, and motor scale

The results of the SEM pain rating scale are shown in Table 3. Analysis showed that 75% of children receiving buffered lidocaine experienced no pain, whereas 5% experienced moderate discomfort. Of the children receiving non-buffered lidocaine, 55% reported no pain, while 17.5% reported moderate discomfort. The Mann-Whitney test identified a significant difference between buffered and non-buffered lidocaine (Tables 3,4; $p =$ 0.043).

TABLE 2. Wong-baker faces pain rating scale.

Pain level	N	%	N	%
	Buffered		Non-Buffered	
0	29	72.5%	18	45.0%
2	10	25.0%	15	37.5%
4	1	2.5%	5	12.5%
6	0	0.0%	2	5.0%
8	0	0.0%	0	0.0%
10	0	0.0%	0	0.0%
Total	40	100.0%	40	100.0%

Note: N: number; %: Percent.

5.2 Onset of anesthesia

The mean onset time for soft tissue anesthesia for non-buffered lidocaine was 7 minutes and 38 seconds; this compared to 3 minutes and 66 seconds for buffered lidocaine (Table 5). The mean onset time for pulpal anesthesia for buffered lidocaine was 5 minutes and 34 seconds; this compared to 11 minutes and 34 seconds for non-buffered lidocaine (Table 5). The student's *t*-test for independent samples revealed a significant difference in the onset time of soft tissue and pulpal anesthesia between buffered and non-buffered lidocaine (Table 5; $p = 0.001$).

TABLE 3. Differences in the Wong-Baker FACES pain rating scale and the SEM pain scale results, as determined by the Mann-Whitney test.

	N	Mean	Sum of ranks	Mann-Whitney test	*p*-Value
Wong-Baker FACES® pain rating scale					
Buffered	40	34.29	1371.5	2.731	0.006
Non-Buffered	40	46.71	1868.5		
SEM pain scale					
Buffered	40	36.08	1443	2.020	0.043
Non-Buffered	40	44.93	1797		

Note: N: number.

TABLE 4. SEM pain rating scale.

Pain level	N	%	N	%
	Buffered		Non-Buffered	
1	30	75.0%	22	55.0%
2	8	20.0%	11	27.5%
3	2	5.0%	7	17.5%
4	0	0.0%	0	0.0%
Total	40	100.0%	40	100.0%

Note: N: number; %: Percent.

TABLE 5. Differences in the time to onset of soft tissue and pulpal anesthesia, as determined by the student's *t*-test.

	N	Mean	SD	*t*-test	DOF	*p*-Value
Onset of soft tissue anesthesia						
Buffered	40	3.66	0.868	11.623	78	0.001
Non-Buffered	40	7.38	1.828			
Onset of pulpal anesthesia						
Buffered	40	5.34	0.675	14.114	78	0.001
Non-Buffered	40	11.34	2.601			

Note: N: number; SD: Standard deviation; DOF: The Degree of Freedom.

6. Discussion

Theoretically, raising the pH of an anesthetic solution can eliminate or at least minimize the pain on injection, slow the onset and reduce the efficacy of anesthesia in the presence of infection [6]. In this study, we followed the split-mouth technique in order to reduce individual differences between different subjects, including pain threshold. In the first session, each child received buffered or non-buffered lidocaine. However, in the next session, which was scheduled one week later, we administered the other solution; this removed the effect of the first anesthetic solution. In total, 40 children (of both genders) were included; most were female. However, there was no significant effect of gender on pain measurements.

The majority of previous research on the responses of children to experimental pain found no significant gender differences in pain-related outcomes in children under the age of 12, the age that is traditionally associated with the onset of pubertal development in both boys and girls [18]. Cooperative children (positive or absolutely positive), according to Frankl's behaviour rating scale, were included while children who were unable to cooperate were excluded.

According to several studies that evaluated the effectiveness of buffered lidocaine in adults, Kattan *et al.* [19] (2019) concluded that buffered local anesthesia is more effective than non-buffered local anesthesia. A randomised controlled trial, conducted by Koja *et al.* [20] (2022) further reported that buffered local anesthesia eliminated injection pain on the buccal area and palate during the extraction of maxillary premolars and molars and had a faster onset of anaesthesia when compared to non-buffered local anesthesia. In addition, a study conducted by Kalra *et al.* [21] (2023) compared the efficacy and onset of anesthesia using buffered local anesthesia in adults and found that buffering local reduced the onset time of anesthesia and increased the effectiveness of local anesthetics. Jain *et al.* [22] (2022) reported that buffered lidocaine had a faster onset time of anesthesia with the same efficacy of non-buffered lidocaine during inferior alveolar nerve block.

In the present study, we used the Wong-Baker FACES (WBS) facial pain rating scale for subjective pain evaluation, while the SEM scale was used for objective pain assessment. We used both scales because it is very difficult to quantify

pain in children. The Wong-Baker FACES facial pain rating scale (Fig. 2) used in this study complied with the American Academy of Pediatric Dentistry guidelines on pain assessment. Ethnic, cultural and language factors can influence the expression of pain and its assessment. The experience of pain can also shape a child's perception of pain in the future. Self-reported pain assessment remains the gold standard for pain assessment [7]. A comparison of the WBS pain scale between buffered lidocaine and non-buffered lidocaine revealed a significant difference. Most of the children reported that they felt no pain during the injection of IANB with buffered lidocaine. In addition, a highly statistical difference was detected between buffered and non-buffered lidocaine when assessed objectively. Observing a child's response during injection by three external pedodontics investigators revealed that most of the children felt no pain in response to buffered lidocaine. These results were in agreement with those previously reported by Afsal *et al.* [23] (2019) who reported that buffered lidocaine was the least painful and most effective anesthetic agent during the injection of inferior alveolar nerve block injection in children aged 5 to 10 years. These authors compared pain using the WBS pain scale and the SEM scale between non-buffered lidocaine, buffered lidocaine and articaine. The findings from this previous study were in line with those reported by Kurien *et al.* [17] (2018) in a study that involved children aged 6 to 12 years who needed pulp therapy bilaterally on the mandibular primary molars and compared non-buffered, buffered, or pre-warmed 2% lidocaine using objective and subjective scales. These authors discovered that buffering or pre-warming the anesthetic solution reduced pain in children during both administration and procedures. In contrast, Chopra *et al.* [9] (2016) reported that buffered lidocaine did not reduce the pain associated with IANB injections in children aged 6 to 12 years. These discrepancies may be due to the different pain scales being used.

By using buffered lidocaine, it is expected that the body will convert the solution from an ionized to a unionized form more quickly, thus improving nerve penetration and accelerating the onset of the anesthetic effect. Studies in adult populations reported a faster onset of anesthesia when using buffered lidocaine solutions when compared to non-buffered solutions. For example, Kashyap *et al.* [24] (2011) confirmed the efficacy of buffered local anesthetic solution in reducing pain on injection and resulting in a quicker onset of anesthesia. These studies assessed the onset time of soft tissue anesthesia. However, it is known by all practicing dentists and from the results of well-designed clinical trials, that the anesthesia of soft tissues (*e.g.*, the lips and tongue) is not a guarantee of pulpal anesthesia [6]. There is a significant practical and clinical distinction between the onset of soft tissue anesthesia and the onset of pulpal anesthesia [6]. Malamed *et al.* [25] (2013) evaluated the onset time of anesthesia and the efficacy of buffering local anesthesia for IANB in 20 healthy adults. The average onset time of pulpal anesthesia, as measured using Endo-Ice after ensuring lower lip numbing, was under two minutes for buffered lidocaine compared to over six minutes for non-buffered lidocaine. In the present study, we evaluated the average onset time of soft tissue anesthesia by probing the gingiva every 15 seconds after ensuring the numbness of the tongue, lower lip and the angle of the mouth; the onset time was significantly reduced from 7.38 minutes for non-buffered lidocaine to 3.66 minutes for buffered lidocaine. In addition, the onset time of pulpal anesthesia was 5.34 minutes for buffered lidocaine compared to 11.34 minutes for non-buffered lidocaine.

A previous study conducted by Baker *et al.* [26] (2021) found that the onset of soft tissue anesthesia was the same for both buffered and non-buffered anesthetic solutions based on soft tissue numbness in children undergoing treatment with 1% buffered lidocaine and 2% non-buffered lidocaine. This difference may be due to the different concentrations of lidocaine used. In another study, Lai *et al.* [27] (2006) found that 85% of patients achieved soft tissue anesthesia, as determined with a sharp dental explorer, and 40% for pulpal anesthesia determined with an EPT (Electronic pulp tester) at 6 minutes after IANB with 2% lidocaine with epinephrine at a dilution of 1:100,000.

7. Conclusions

Our analysis showed that 2% buffered lidocaine with 1:80,000 epinephrine shortened the onset time of pulpal and soft tissue anesthesia and reduced the pain experienced during IANB injections in children when compared to non-buffered lidocaine with 1:80,000 epinephrine.

8. limitation of this study

The major limitations of this study were sample size and the age of the patients. In future, research should focus on younger children and include larger sample sizes.

AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available on request from the corresponding author. Data are available upon request due to privacy from the corresponding author.

AUTHOR CONTRIBUTIONS

RH—conceived the idea and provided the treatment. CK and HA—supervised the treatment. IA—contributed to the writing and documenting.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This randomised, triple-blind, split-mouth controlled study was conducted in the Department of Pedodontics at Damascus University. Approval from the Institutional Ethical Board of Damascus University was obtained before conducting the research according to the Helsinki Declaration 2013 and to CONSORT statement (427-15-3-2022). The current clinical trial was registered and approved by ClinicalTrials.gov (NCT05793905). Detailed written informed consent was obtained from patients' legal guardians before enrolling the pa-

tients in the study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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